

REMARKS/ARGUMENTS

Claims 1-15, 58 and 68 were pending. Claims 1, 2, 5, 7, and 14 have been amended herein. Claims 58 and 68 have been cancelled without intending to abandon or to dedicate to the public any patentable subject matter.

Rejections Under 35 U.S.C. § 112, Second Paragraph

The Examiner has rejected Claims 1-15, 58 and 68 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. Claims 58 and 68 have been cancelled. Claims 1, 2, 5, 7 and 14 have been amended.

Claim 1 has been amended to recite detecting a maternal antibody from the mother bound to a paternally-inherited fetal antigen on a fetal cell, to thereby identify the fetal cell. Furthermore, Claim 1 has been amended to recite elements to effect detecting of a maternal antibody from the mother. In light of these amendments, Applicants submit that Claim 1, as currently amended, is in condition for allowance and Applicants respectfully request that the rejection be withdrawn.

The Examiner objects to Claim 2 as confusing. Applicants have amended Claim 2 to clarify that the maternal antibody is contacted with an agent capable of forming a complex with the maternal antibody, and Applicants believe that these amendments overcome the Examiner's objections to this claim.

The Examiner states that Claim 5 is indefinite for omitting essential structural and functional cooperative relationships of the elements. Applicants have amended Claim 5 to comprise detecting a maternal antibody from the mother, bound to a fetal cell, wherein the maternal antibodies comprise maternally-produced antibodies specific for paternally-inherited fetal antigens, to thereby identify the fetal cell. Furthermore, Claim 5 has also been amended to recite elements to effect detecting of a maternal antibody. In light of these amendments, Applicants submit that claim 5 is sufficiently definite to meet the requirements of 35 U.S.C. § 112, second paragraph.

The Examiner also rejects Claim 7 as indefinite, arguing that it is unclear how an actual positive complex formation is effected. Claim 7 has been amended to recite contacting the maternal antibody bound to a fetal cell with an agent capable of forming a complex with the maternal antibody. In light of these amendments, Applicants submit that claim 7 is also sufficiently definite to meet the requirements of 35 U.S.C. § 112, second paragraph.

The Examiner also makes reference to claim 14, although the objection to this claim is not specifically recited. Applicants have amended Claim 14 such that the step of detecting the fetal cell-maternal antibody complex includes contacting the cells bound by agent-maternal antibody complex to a magnet. Similar to Claim 5, Applicants submit that Claim 14 is sufficiently definite to meet the requirements of 35 U.S.C. § 112, second paragraph.

Claim Rejections Under 35 U.S.C. § 102

The Examiner has rejected Claims 5, 7-9, 11-13 and 15 under 35 U.S.C. § 102(b) as being anticipated by Warwick et al. (Detection strategy for maternal antibodies against paternal HPA-1 antigen, *The Lancet* 344: page 64 (July 2, 1994)).

The Examiner asserts that Warwick et al. teaches obtaining an amniotic fluid sample containing one or more fetal cells which carry a paternally-inherited fetal antigen (HPA-1), and detecting maternal antibodies bound to the paternally-inherited fetal antigen, where the detection of fetal susceptibility to the maternal antibodies can be performed using immunofluorescence testing whereupon the fetal cells are contacted with a detectably-labeled agent that forms a complex with the maternal antibody that is bound to paternally-inherited fetal antigen.

But Warwick et al. fails to disclose using maternal antibodies to identify fetal cells. In particular, Warwick et al. refer to the maternal antibody binding antigens on “paternal platelets” rather than the fetal cells. (*See* Warwick et al. page 64, col. 2, third paragraph). In other words, Warwick et al. teaches the use of maternal antibodies to determine the genotype/phenotype of the father, but not to identify and/or enrich a fetal cell. Thus, Warwick et al. fails to disclose each element of claim 5, as currently amended, and Applicants submit that Claim 5 is in condition for allowance and respectfully request the Examiner’s rejection of this claim under 35 U.S.C. § 102(b) be withdrawn.

Applicants submit that Claims 7-9, 11-13 and 15 are at least allowable based on their dependency to Claim 5, as amended.

Rejections Under 35 U.S.C. § 112, First Paragraph

The Examiner has rejected Claims 1-15, 58 and 68 under 35 U.S.C. § 112, first paragraph, for failing to comply with the enablement requirement. Claims 58 and 68 have been cancelled. “The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation.” MPEP 2164.01m citing *United States v. Teletronics, Inc.*, 857 F.2d 778, 785 (Fed. Cir. 1988).

The Examiner asserts that while the specification is enabled for a method of identifying and enriching fetal cells carrying a paternally-inherited fetal HLA antigen using purified maternal antibodies that are dissociated and extracted specifically from complexes formed with known HLA antigens in maternal plasma deemed to be HLA antigens inherited paternally, the specification does not reasonably provide enablement for the claimed method using generic maternal antibodies or maternal antibodies from any maternal plasma sample dissociated from all complexes formed with soluble HLA antigen and/or anti-idiotypic antibody. Applicants submit that the claimed invention is not about “generic antibodies” or using maternal antibodies from a source other than the mother. To clarify this point, Claims 1 and 5 have been amended to specify that the maternal antibody is from the mother of the fetus, from which the fetal cell is derived.

Applicants also note that the Examiner’s comments focus on HLA antigens, however, the antigen can be any paternally-inherited antigen not expressed by the mother; HLA or otherwise.

In view of the foregoing remarks and amendments, applicants submit that there is adequate enablement in the specification for Claims 1-15, as amended, and request the Examiner’s rejection under 35 U.S.C. § 112, first paragraph, be withdrawn.

Based upon the foregoing, Applicants believe that all pending claims are in condition for allowance and such disposition is respectfully requested. In the event that a telephone conversation would further prosecution and/or expedite allowance, the Examiner is invited to contact the undersigned.

Respectfully submitted,
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